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(54) Title: CRYOGENIC SYSTEM

(57) Abstract: A cryosurgical system and method for supplying cryogen to a probe. The system including a container filled with cryogen and having bellows of a pump submerged within said cryogen. Conduits fluidly interconnect the bellows and a probe that is outside the container to permit the cryogen to be forced from the bellows to the probe upon activation of pump. A pressure relief valve is fluidly coupled to the conduits and positioned between the bellows and the probe. After initially forcing cryogen to the probe at a pressure that establishes a colligative-based sub-cooling of the liquid cryogen, the pressure relief valve is activated to lower the pressure of the cryogen to a running pressure.

CRYOGENIC SYSTEM

This application claims the benefit of U.S. Provisional Application Serial No. 60/294,256, filed on May 31, 2001, the entire contents of which are hereby incorporated herein by reference thereto.

Field of the Invention

The present invention relates to a cryogenic system. More specifically, illustrative embodiments of the present invention relate to a cryogenic system for use in cryosurgical procedures.

Background

The distribution of boiling (liquid) cryogens, such as liquid nitrogen, is problematic due to the parasitic heat load provided by a cryosurgical device's plumbing or transport circuit, which is maintained at ambient temperature. Pre-cooling the plumbing circuit, even if adequately insulated, causes two-phase flow (liquid-gas mixtures), cryogen boil-off, and choking flow due to gas expansion in the transport circuit. As a result, target temperatures at the distal end of the flow path (i.e., cryoprobe tip) are not reached for many minutes.

Some prior cryogenic systems and devices are disclosed in U.S. Patent Nos. 4,345,598 to Zobac et al.; 4,472,946 to Zwick; 4,860,545 to Zwick et al.; 4,946,460 to Merry et al.; 5,254,116 to Baust et al.; 5,257,977 to Eshel; 5,334,181 to Rubinsky et al.; 5,400,602 to Chang et al.; 5,573,532 to Chang et al.; and 5,916,212 to Baust et al., the entire contents of each being hereby incorporated herein by reference thereto, respectively.

Summary

The present invention can be embodied in a cryosurgical system, comprising a container having cryogen within the container; a pump having a piston submerged within the cryogen; a probe outside the container for use in cryosurgical procedures; a system of conduits fluidly interconnecting the piston and the probe permitting the cryogen to be forced from the piston to the probe upon activation of the piston; and a

pressure relief device fluidly coupled to the systems of conduits and positioned between the bellows and the probe.

The present invention may also be embodied in a pump assembly for a cryosurgical system, comprising a driving mechanism coupled to an elongated drive shaft; a bellows coupled to the drive shaft and adapted to be submersed in cryogen, the bellows formed from metal; a one-way inlet valve fluidly coupled to the bellows; and a one-way outlet valve fluidly coupled to the bellows.

The present invention may also be embodied in a method of delivering cryogen to a surgical device, comprising providing a container having cryogen within the container; providing a pump having a piston within a cylinder and submerged within the cryogen; providing a surgical instrument outside the container for use in cryosurgical procedures; providing a system of conduits fluidly interconnecting the piston and the surgical instrument permitting the cryogen to be forced from the piston to the probe upon activation of the piston; providing a pressure relief device fluidly coupled to the systems of conduits and positioned between the bellows and the probe; activating the piston to pull cryogen within the cylinder; activating the piston to push the cryogen from the cylinder to the surgical instrument at an initial predetermined pressure.

Other aspects, features, and advantages of the present invention will become apparent from the following detailed description of the illustrated embodiments, the accompanying drawings, and the appended claims.

Brief Description of the Drawings

FIG. 1 illustrates a system in accordance with an embodiment of the present invention and includes a cross-sectional view through a container holding cryogen;

FIG. 2 is an enlarged, elevational view of the container of FIG. 1 and its contents;

FIG. 3 is an enlarged, top view of the assembly within the container of FIG. 1;

FIG. 4 is a top view of a valve used in the system illustrated in FIGS. 1-3;

FIG. 5 is an elevational view of the valve of FIG. 4;

FIG. 6 is a schematic view of the system illustrated in FIG. 1 and showing the system as the bellows pulls cryogen within the cylinder;

FIG. 7 is a schematic view similar to FIG. 6 but showing the system as the bellows initially pushes cryogen to the probe; and

FIG. 8 is a schematic view similar to FIGS. 6 and 7 but showing the system as the bellows pushes cryogen to the probe and with the pressure relief valve activated to control the fluid pressure.

Detailed Description of Illustrated Embodiments

FIGS. 1-8 illustrate a preferred embodiment of a cryogenic pump, system, and method according to the present invention. The system 10 provides instantaneous sub-cooling of liquid cryogen 14, thereby creating a cryogen state characterized by an excess capacity to absorb heat without boiling. By manipulating the pressure relationships in the plumbing circuit 26, sub-cooled liquid 214 is transported to the distal cryoprobe tip 130 in 1-20 seconds allowing near instantaneous freezing at the probe tip 130. This rate of cooling is faster and the attainable low temperature is lower than comparable Joule-Thompson-based cryogenic devices.

The illustrated system 10 includes a container or dewar 12 containing cryogen 14, such as liquid nitrogen. A support 16 is positioned within the container 12 and submerged within the cryogen 14. A pump 18 is coupled to the container 12 such that the piston 56, illustrated in the form of a bellows, is also submerged within the cryogen 14. By way of a conduit system 26, the bellows 56 is fluidly coupled to an output manifold 20, a pressure release valve 22, and a surgical probe 24. A control system 28 monitors the temperature of the probe tip 130 and adjusts the system components as necessary to maintain the desired temperature at probe tip 130.

The container 12 is of substantially conventional design, except that it is appropriately adapted to support pump 18. Pump 18 includes a linear drive motor 52 mounted outside the container 12 and, preferably mounted to the top of the container 12. A drive shaft 54 extends down from the motor 52, through the

cryogen 14 and couples to the bellows 56. The bellows 56 is appropriately constructed to fit within a cylinder 58. Bellows 56 is preferably formed from stainless steel. Also, although the figures illustrate a system 10 with two bellows 56, any appropriate number of bellow systems may be employed. The cylinder 58 has a one-way inlet valve 60 coupled to an inlet conduit 62, and a one-way outlet valve 64 coupled to an outlet conduit. The cylinder 58 and bellows 56 assembly is rigidly secured to the support 16 along with manifold 20.

Manifold 20 has an inlet conduit 80 fluidly coupled to the outlet valves 64 of the bellows 56. Manifold 20 also has outlet conduits 82 fluidly coupled to the probe 24. Although five outlet conduits 82 are illustrated it should be understood that the number of outlet conduits 82 is dependent on the system requirements, and that more or fewer outlet conduits 82 may be used. The manifold 20 also has an outlet port 84 for coupling with the pressure relief valve 22.

Pressure relief valve 22 is preferably mounted outside the container 12 and is coupled to the manifold by inlet conduit 100. The valve 22 also has an outlet conduit that leads back into the cryogen 14 in container 12 to return, to the container 12, the cryogen 14 that has been released from the conduit system 26 to lower the pressure as desired.

The surgical apparatus illustrated is shown as probe 24 with its corresponding tip 130 and is intended to represent any appropriate cryosurgical device, including probe tips, such as those known in the prior art. Examples of prior art probes are disclosed in the patents incorporated herein as set forth above.

Thus, the illustrated embodiment includes a reciprocating stainless steel bellows pump 18 that operates while submerged in liquid cryogen 14 and that causes instantaneous sub-cooling of the liquid cryogen 14 during the compression stroke of the bellows 56, thereby creating a cryogen state characterized by an excess capacity to absorb heat without boiling. Further, by manipulating the pressure relationships in the plumbing circuit 26, sub-cooled liquid 214 is transported to the distal cryoprobe tip 130 in 1-20 seconds allowing near instantaneous freezing at the probe tip 130.

In the illustrated embodiment, one or more stainless steel bellows "pistons" 56 are driven by a surface mounted linear drive system 52 capable of pressure regulation. The reciprocating action of each bellows piston 56 a) sequentially produces a negative préssure to draw in liquid cryogen 14 on the fill stroke through a one-way check valve 60 and b) sequentially discharge liquid cryogen 214 at a prescribe pressure profile out through a second one-way check valve 64 to a pressure manifold 20 connected to the probe 24 plumbing circuitry. The preferred, prescribed profile is a range of between 250 pounds per square inch (psi) and 400 pounds per square inch (psi).

The pressure pulse profile establishes an initial high, transient pressure spike that causes a colligative-based sub-cooling of the liquid cryogen 14, which establishes a boiling point differential of approximately 30-40 degrees Celsius, thereby establishing an excess temperature capacity (the level of temperature rise that can be allowed before boiling of the cryogen 14) supporting the instantaneous distribution of sub-cooled cryogen 214 in the plumbing circuit 26. Following the transient pressure spike, pressure is reduced to a base level to sustain the desired rate of ice growth a the distal end of the circuit, that is, at the probe 24. Conventional control system technology can be employed in controlling the interaction between the probe 24 and the pressure relief valve 22 and/or the pump 18, that is, in producing the control system 28

Pressure relief and control is provided by an appropriately designed pressure transducer-valve interface 22 outside the cryogen-containing dewar 12.

Thus, while the invention has been disclosed and described with reference with a limited number of embodiments, it will be apparent that variations and modifications may be made thereto without departure from the spirit and scope of the invention and various other modifications may occur to those skilled in the art. Therefore, the following claims are intended to cover modifications, variations, and equivalents thereof.

WHAT IS CLAIMED IS:

1. A cryosurgical system, comprising:

a container having cryogen within said container;

a pump having a piston submerged within said cryogen;

a probe outside the container for use in cryosurgical procedures;

a system of conduits fluidly interconnecting said piston and said probe permitting said cryogen to be forced from said piston to said probe upon activation of said piston; and

a pressure relief device fluidly coupled to said systems of conduits and positioned between said bellows and said probe.

2. A system according to claim 1, wherein

said cryogen is liquid nitrogen.

3. A system according to claim 1, wherein:

said piston is a bellows.

4. A pump assembly for a cryosurgical system, comprising:

a driving mechanism coupled to an elongated drive shaft;

a bellows coupled to said drive shaft and adapted to be submersed in cryogen, said bellows formed from metal;

a one-way inlet valve fluidly coupled to said bellows; and

a one-way outlet valve fluidly coupled to said bellows.

5. A pump assembly according to claim 4, further comprising:

a supply manifold fluidly coupled with said outlet valve, said supply and manifold having a plurality of outlet ports.

6. A method of delivering cryogen to a surgical device, comprising:

providing a container having cryogen within the container;

providing a pump having a piston within a cylinder and submerged within the cryogen;

providing a surgical instrument outside the container for use in cryosurgical procedures;

providing a system of conduits fluidly interconnecting the piston and the surgical instrument permitting the cryogen to be forced from the piston to the probe upon activation of the piston;

providing a pressure relief device fluidly coupled to the systems of conduits and positioned between the bellows and the probe;

activating the piston to pull cryogen within the cylinder;

activating the piston to push the cryogen from the cylinder to the surgical instrument at an initial predetermined pressure.

7. A method according to claim 6, wherein

the activating the piston to push the cryogen from the cylinder to the surgical instrument at an initial predetermined pressure includes pushing the cryogen to the surgical instrument at a pressure of between approximately 250 pounds per square inch and approximately 400 pounds per square inch.

8. A method according to claim 6, wherein

after pushing the cryogen to the surgical instrument at the initial predetermined pressure, activating the pressure release device to decrease the pressure of the cryogen to a lower pressure that is below the predetermined pressure.

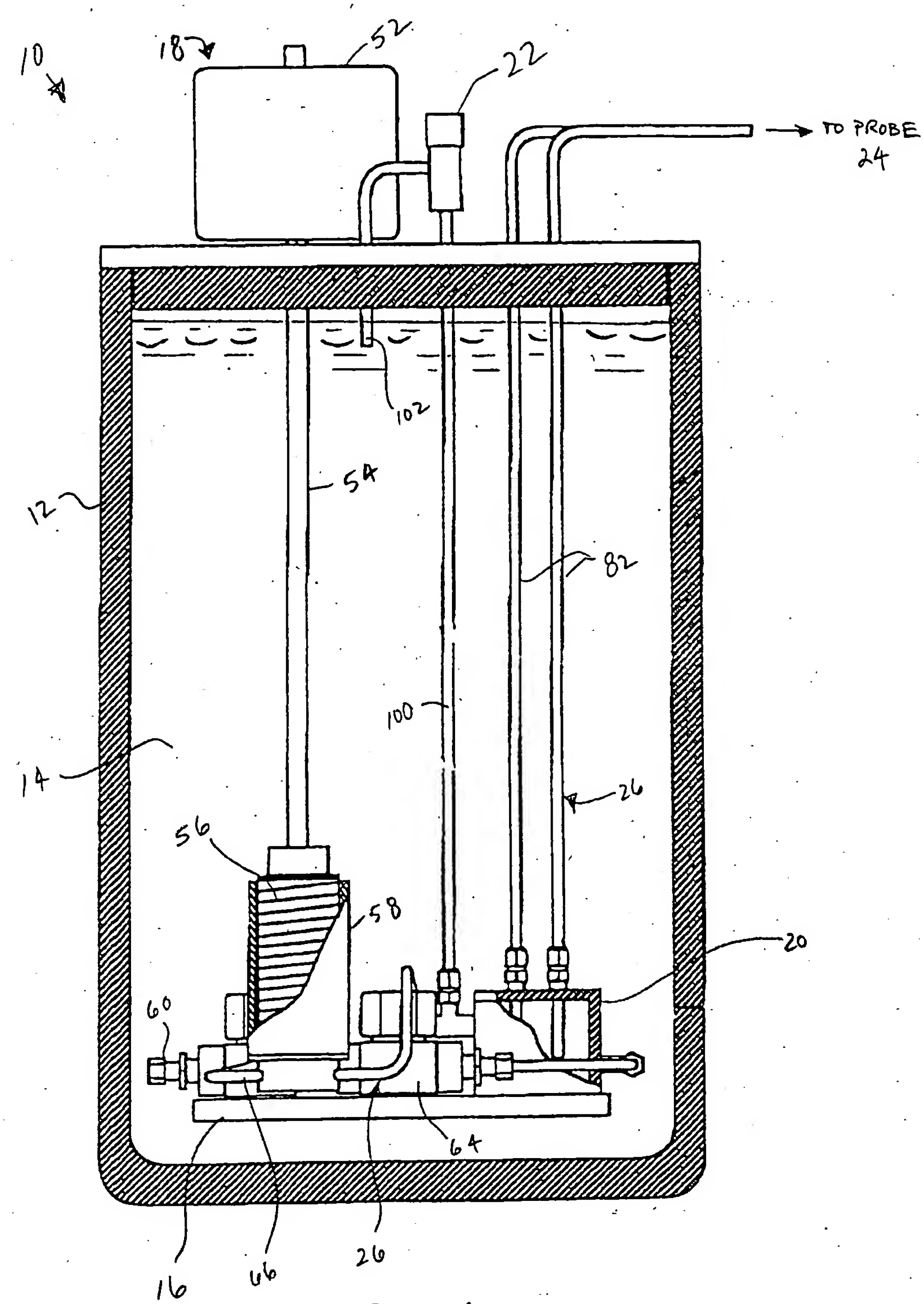
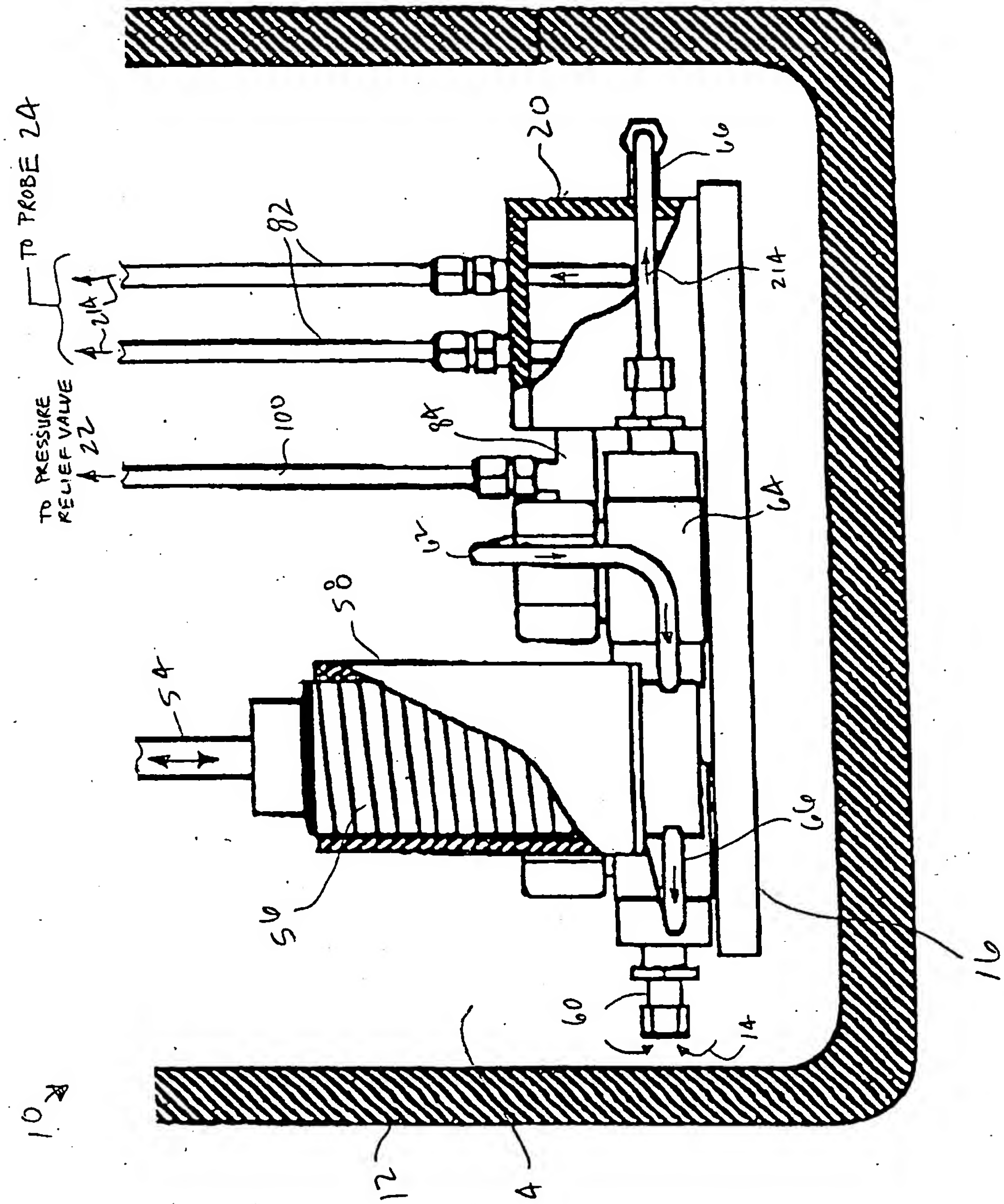


FIG. 1


TO PROBE 24
TO PRESSURE RELIEF VALVE 22
10
12
14
16
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54
56
58
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62
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100
214

FIG. 2

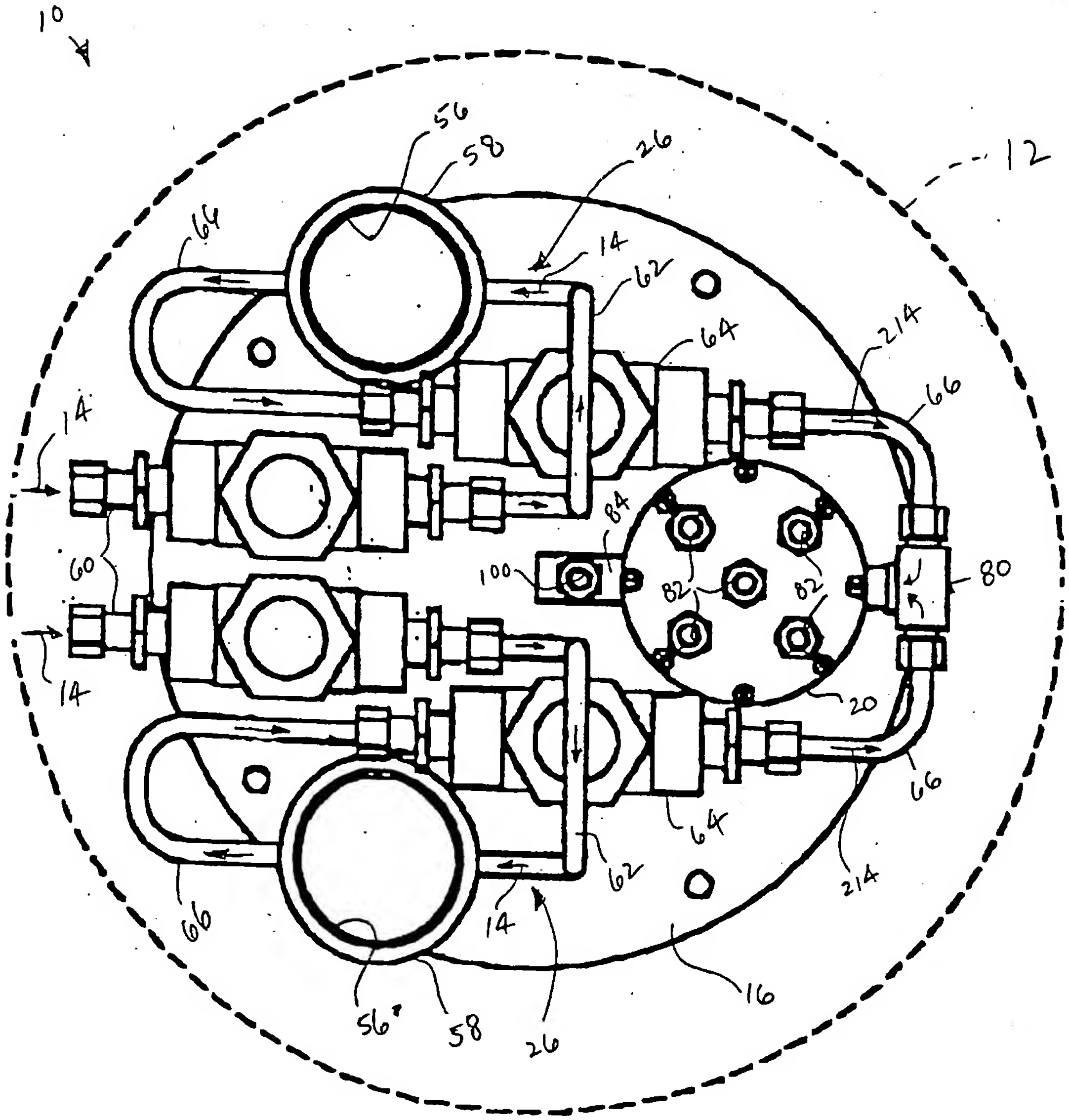
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FIG. 3

FIG. 4

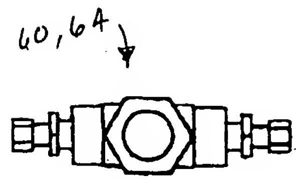
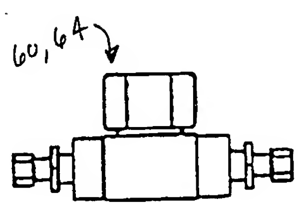


FIG. 5



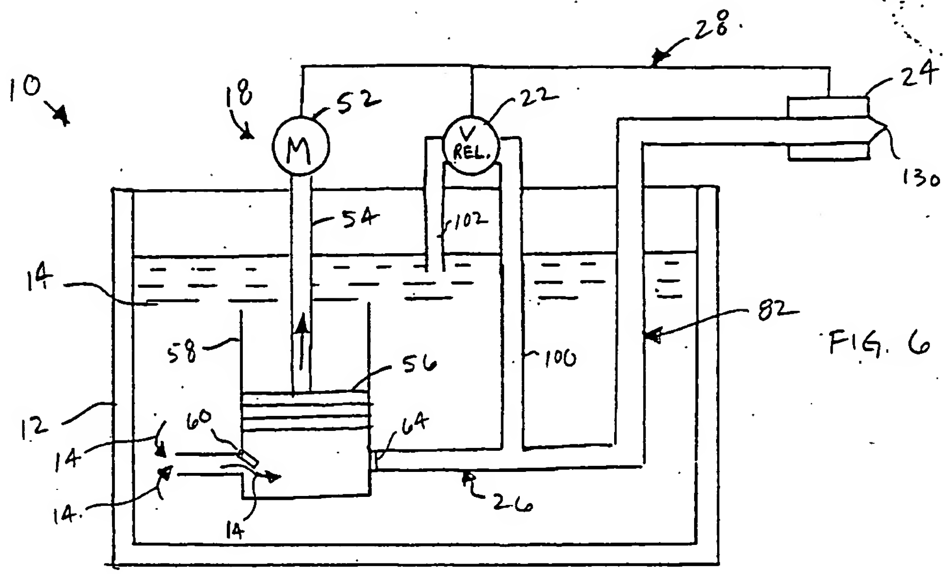


FIG. 6

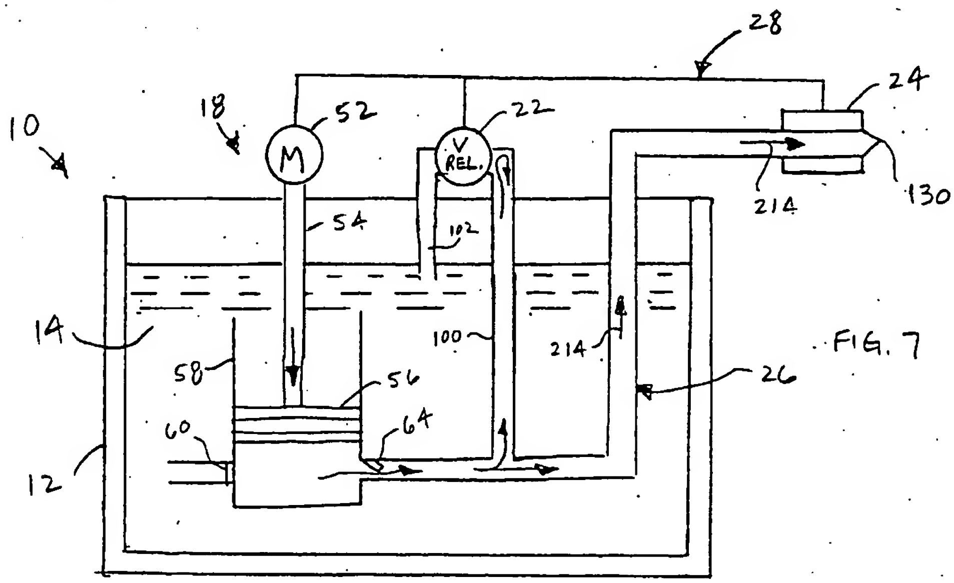


FIG. 7

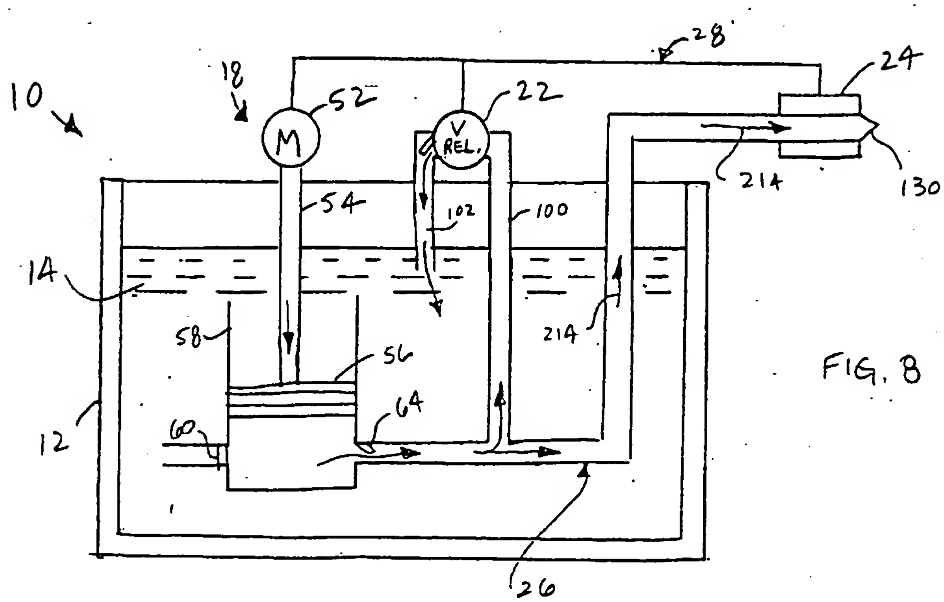


FIG. 8

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(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BAUST, John, G.** [US/US]; 175 Raish Hill Road, Candor, NY 13743 (US). **CHEEKS, Roy** [US/US]; 1207 Fox Drive, Harpers Ferry, WV 25425 (US).

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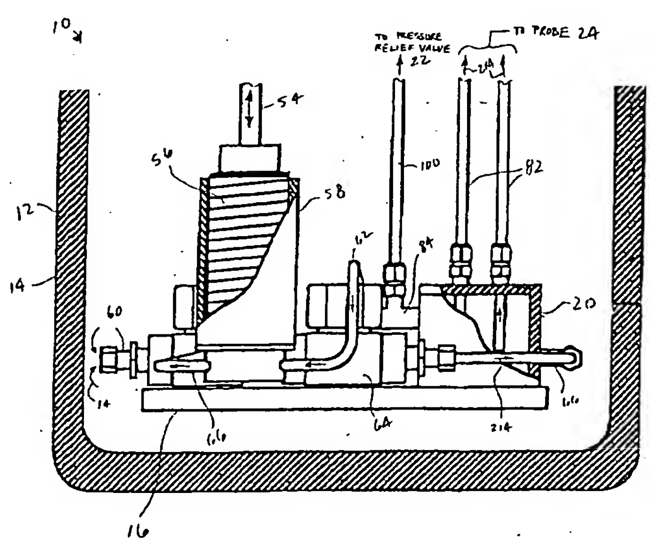
(54) Title: CRYOGENIC SYSTEM



(57) Abstract: A cryosurgical system and method for supplying cryogen to a probe (24). The system including a container filled with cryogen and having bellows (56) of a pump (18) submerged within said cryogen. Conduits fluidly interconnect the bellows (56) and a probe (24) that is outside the container to permit the cryogen to be forced from the bellows to the probe upon activation of pump (18). A pressure relief valve (22) is fluidly coupled to the conduits and positioned between the bellows (56) and the probe (24). After initially forcing cryogen to the probe at a pressure that establishes a colligative-based sub-cooling of the liquid cryogen, the pressure relief valve (22) is activated to lower the pressure of the cryogen to a running pressure.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/22-26

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,957,963 A (DOBAK, III) 28 September 1999, see entire document.	1-4
X	US 5,916,212 A (BAUST et al) 29 June 1999, see entire document.	4-6
A	US 3,613,689 A (CRUMP et al) 19 October 1971, see entire document.	1-8
Y	US 5,947,960 A (GRISWOLD) 07 September 1999, see figures 1-2, item 18.	5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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